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Express Mail Label No. EV 116913533 US

S-PTO
60/544205
0215102151
021204**INVENTOR(S)**

Given Name (first and middle if any)	Family Name or Surname	Residence (City and either State or Foreign Country)
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Additional inventors are being named on the _____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)**Pressure Sensing**

Direct all correspondence to:

CORRESPONDENCE ADDRESS Customer Number:

24994

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ENCLOSED APPLICATION PARTS (check all that apply)

<input checked="" type="checkbox"/> Specification Number of Pages 18	<input type="checkbox"/> CD(s), Number _____
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets 4	<input checked="" type="checkbox"/> Other (specify) Return Card
<input type="checkbox"/> Application Date Sheet. See 37 CFR 1.76	

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

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[Page 1 of 2]

Date 02 - 12 - 04

Respectfully submitted,

SIGNATURE Laura M. Butterfield

REGISTRATION NO. 47466

(if appropriate)

Docket Number. N0105-US01

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In re Application of: JÖNSSON, Lennart, DROTT, Johan}
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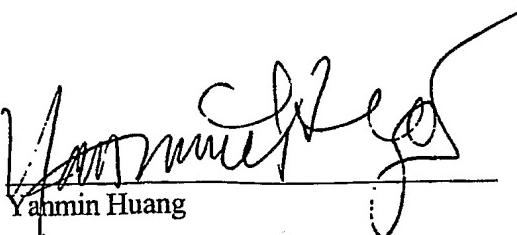
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PRESSURE SENSING

Technical field

The present invention relates to management of fluids used in a medical procedure and more specifically to pressure sensing in a biological fluid.

5 Background

There are a number of procedures in which biological fluids are managed. Examples of such procedures include peritoneal dialysis and other treatments where blood is taken out in an extracorporeal blood circuit. Such 10 treatments involve, for example, hemodialysis, hemofiltration, hemodiafiltration, plasmapheresis, blood component separation, blood oxygenation, etc. Normally, blood is removed from a blood vessel at a blood access and returned to the same blood vessel.

15 During these procedures it is often desirable and also important to monitor the pressure in the biological fluid system. In peritoneal dialysis, occasionally intraperitoneal pressure is measured in order to determine maximum tolerated fill volume of the peritoneum 20 of an individual patient. This may be done by measuring the height of a liquid column in an open tube connected to the peritoneum. This measurement method is inconvenient for the patient. Moreover, the accuracy of the resulting measurement could sometimes be questioned 25 as it is based on a number of estimations.

US Patent application 20020007137 describes a prior art dialysis pressure sensing system wherein the pressure in an extracorporeal blood circuit is measured with an ordinary pressure transducer.

30 Typically, when performing pressure sensing using arrangements according to prior art, the extracorporeal blood circuit is connected to a patient and a dialysis machine. The pressure sensor is located within the dialysis machine and operably and structurally connected 35 to the extracorporeal blood circuit.

Even though the extracorporeal blood circuit typically is in the form of a disposable arrangement there is a risk of cross contamination between patients.

Between the pressure sensor in the dialysis machine and

5 the blood in the disposable extracorporeal circuit is arranged an air column in a connector line/column. The air column exerts a backpressure on the blood, thereby preventing blood from getting in contact with the pressure sensor/machine. The dialysis machine normally

10 comprises pumps of roller type creating a pulsating flow of blood in such a way that blood is penetrating into the connector line to some extent. In case the blood flow is blocked there is a potential risk that the backpressure exerted on the blood by the air column in the connector

15 line is overcome and that blood reach a protective filter, protecting the pressure sensor. In such a case, cross contamination could occur if this situation reoccurs with another patient connected to the machine and the machine has not been cleaned properly. Also there

20 is a potential risk that bacteria could grow in blood residuals at the protective filter.

Another problem is that of leakage, which may occur due to operator mistakes during set-up of the system. Needless to say, leakage could be of danger to an

25 operator of the system in case contaminated blood is present in the system. Leakage may also lead to erroneous or less accurate pressure measurements.

Thus, there is a general problem of how to provide a disposable fluid arrangement which is easy to set-up,

30 avoid leakage and which reduces the risk of cross contamination between patients and/or operators of the system.

An object of the present invention is to provide a system capable of overcoming problems related to prior art systems.

The object of the present invention is achieved by 5 way of a device according to claim 1, a use according to claim 27 and a system according to claim 32.

An inventive device for containing or transporting medical and/or biological fluid comprises at least one sensor capable of sensing at least a first characteristic 10 of the fluid. The sensor is also capable of wireless communication of information where said information is related at least to the sensed characteristic of the fluid.

In preferred embodiments of the invention, the 15 sensor is capable of sensing pressure and the device is preferably a disposable part of either an extracorporeal blood circuit or an intraperitoneal dialysis system.

The pressure sensor may be arranged within the device, which is the case when a device according to the 20 invention is used as a disposable part of an extracorporeal blood circuit.

The pressure sensor may also be arranged on the outside of the device in fluid communication with the fluid within the device during use. This may be the case 25 for example when the device is to be used in peritoneal dialysis. In this case a catheter is inserted into the abdominal cavity of a patient. The pressure sensor may in this case be arranged at the outside of the catheter close to the end of the catheter such that the sensor is 30 inside the patient during dialysis.

In an embodiment where the pressure sensor is located at a cavity it is possible to obtain a value for the pressure by measuring the compression of the cavity. It is to be noted that the term compressible means that 35 the volume of the device may increase as well as decrease depending on the pressure surrounding the container.

The sensor, in its wireless communication capability, is capable of communicating information by means of waves. The waves may be electromagnetic (including radio, optical etc.) or mechanical (including 5 sonic, ultrasonic, infrasonic etc.).

According to an embodiment of the present invention the pressure sensor may include components in the form of a capacitance and/or an inductance, of which components at least one is a variable component which varies with 10 the relative compression and/or expansion of the container, said capacitance and/or inductance being part of a resonance circuit.

By having such a sensor it is possible to measure the magnitude of the variable component by measuring the 15 resonance frequency. Thus, either the variable capacitance or the variable inductance is measured. From earlier measurements of the variable components dependence of the pressure the pressure may be determined.

20 As an alternative to a resonant circuit, the pressure may be read from the sensor using mechanical/-acoustical or electromagnetic waves from an emitter. In this case the sensor may have a reflecting side arranged for the reflectance of waves from a wave emitter.

25 It may of course also be the case that the sensor is of more complicated type and is only relying on the waves for communicating the measured pressure from the sensor.

According to an embodiment of the present invention a container has two reflecting surfaces of which one is 30 arranged on a compressible wall of the container and the other one is arranged fixed in relation to the wall of the device containing or transporting fluid.

The sensor according to the present invention may 35 preferably comprise a container that at least partly is micromachined. The material chosen for the container may be any material suitable for micromachining. These materials include polymeric materials, metals and also

semiconductors. It may for example be silicon, quartz or any other micromachinable material.

The container may comprise two micromachined parts which together form a container. This is a cost effective
5 way of producing small sensors as such micromachined parts may be batch fabricated components.

At least one of the micromachined parts may comprise a compressible wall which may move with the applied pressure.

10 According to an embodiment of the present invention the micromachined parts may be covered by a conductive layer on sides which are arranged facing each other and which are isolated from each other by an isolating layer or more often a void.

15 The conductive layers separated by the non-conductive cavity then form part of a variable capacitance.

20 The compressible cavity may include a gas such as air at any known pressure, i.e. a reference pressure. The container may have a known fixed pressure therein, so as to have a reference. This could be one way of differentiating the resonant frequency corresponding to a zero pressure point and thus could provide for tailoring the difference of resonant frequency in order to sense
25 the pressure.

30 The sensor may be tailored to have different resonance frequencies in an unaffected state, or comprise a RFID functionality, in order to provide for identifying between different disposables used in different applications, such as dialyser, cassette, bloodline, ultrafilter, RO-filter, catheter, fluid bag, blood bag, collection bags, pump segment part of lineset, connector lineset, dialysis machine fluid path etc.

An advantage of the invention is that, by disposing
35 with the need for structurally connecting a pressure sensor to an extracorporeal blood circuit, thereby minimizing the air-blood interface, risks of cross

contamination between patients and/or operators are avoided.

Another advantage is that it is easy to set-up and thereby avoiding risks of leakage, which may be dangerous
5 to an operator of the system.

Yet another advantage of the present invention is that it provides an integrated pressure sensor which is sufficiently inexpensive to allow each device to be disposed of after each use.

10 Moreover, the invention is advantageously used in an extracorporeal dialysis procedure where the extracorporeal circuit is connected to the patient via a catheter inserted in a subclavia, jugular or femoral vein for regular or temporary use. During this procedure it is
15 of interest to monitor the status of the catheter in order to reveal any complications such as thrombus. This monitoring may be done by means of measuring the pressure of the blood in the catheter.

Also, the invention is advantageously used in peritoneal dialysis procedures, during which it is of
20 interest to monitor the pressure as this parameter may be used for filling of the peritoneal cavity with respect to pressure rather than volume.

The above aspects may be separate or combined in the
25 same embodiment. Preferred embodiments of the present invention will now be described with reference to the accompanying drawings.

Brief description of the drawings

Figure 1 shows schematically an extracorporeal blood
30 circuit connected to a patient.

Figure 2 shows schematically an extracorporeal blood circuit comprising a device according to an embodiment of the present invention.

Figure 3 shows schematically a part of an
35 extracorporeal blood circuit comprising a device with a sensor according to an embodiment of the present invention.

Figure 4 shows part of fig 3 in larger scale.

Figures 5a-5d shows schematically a pressure sensor.

Figure 6 shows schematically a device with a sensor according to an embodiment of the present invention.

5 Figure 7 shows schematically a patient during peritoneal dialysis wherein a catheter is inserted into the patient.

Figures 8 a-c shows schematically the tip of the catheter with a pressure sensor.

10 Description of preferred embodiments

The invention will be described initially by way of illustration of an extracorporeal blood circuit during the process of dialysis followed by a description of a pressure sensor and concluding with a description of an intraperitoneal dialysis system.

Figure 1 discloses a forearm 1 of a human patient. The forearm comprises an artery 2, in this case the radial artery, and a vein 3, in this case the cephalic vein. Openings are surgically created in the artery 2 and the vein 3 and the openings are connected to form a fistula 4, in which the arterial blood flow is cross-circuited to the vein. Due to the fistula, the blood flow through the artery and vein is increased and the vein forms a thickened area downstream of the connecting openings. When the fistula has matured after a few months the vein is thicker and may be punctured repeatedly. Normally, the thickened vein area is called a fistula. As the skilled person will realize, an artificial vein may also be used.

30 An arterial needle 5 is placed in the fistula, in the enlarged vein close to the connected openings and a venous needle 6 is placed downstream of the arterial needle, normally at least five centimeters downstream thereof.

35 The needles are connected to a tube system 7 shown in fig. 2, forming an extracorporeal circuit comprising a blood pump 8, such as may be found in a dialysis circuit.

The blood pump transfers blood from the blood vessel, through the arterial needle, the extracorporeal circuit, the venous needle and back into the blood vessel.

5 The extracorporeal blood circuit 7 shown in Fig. 2 further comprises an arterial clamp 9 and a venous clamp 10 for isolating the patient should an error occur.

10 Downstream of pump 8 is a dialyzer 11 comprising a blood compartment 12 and a dialysis fluid compartment 13 separated by a semi permeable membrane 14. Further downstream of the dialyzer is a drip chamber 15, separating air from the blood therein.

15 Blood passes from the arterial needle past the arterial clamp 9 to the blood pump 8. The blood pump drives the blood through the dialyzer 11 and further via the drip chamber 15 and past the venous clamp 10 back to the patient via the venous needle. The drip chamber may comprise air or air bubbles. The blood circuit also comprises a device capable of containing or transporting fluid 223, within which is located a pressure sensor (not shown in figure 1). The device 223 has the form of a compressible container which in one embodiment has a fixed position in relation to the blood circuit. The device 223 together with a small part of the blood circuit is shown in larger scale in figure 3.

25 The dialysis compartment 13 of the dialyzer 11 is provided with dialysis fluid via a first pump 16, which obtains dialysis fluid from a source of pure water, normally RO-water, and one or several concentrates of ions, metering pumps 17 and 18 being shown for metering such concentrates.

30 An exchange of substances between the blood and the dialysis fluid takes place in the dialyzer through the semi permeable membrane. Notably, urea is passed from the blood, through the semi permeable membrane and to the dialysis fluid present at the other side of the membrane. The exchange may take place by diffusion under the influence of a concentration gradient, so called

hemodialysis, and/or by convection due to a flow of liquid from the blood to the dialysis fluid, so called ultrafiltration, which is an important feature of hemodiafiltration or hemofiltration.

5 Figure 3 shows a section of a part of a blood circuit 30 with a pressure sensor 323 according to the present invention. The sensor 323 may be attached inside a tubing line such as line 70 in figure 2 after the pump 8 leading to the dialyser, as indicated by reference 10 numeral 23'' in figure 2. Alternatively the sensor 323 may be arranged in a tubing line 70 before the pump 8, as indicated by reference numeral 23' in figure 2. As a further alternative the sensor 23 may be arranged in a drip chamber such as drip chamber 15 in figure 2.

15 The pressure sensor 323 comprises a container 25 with a compressible wall 24. A resonance circuit is enclosed by the compressible container and comprises a variable capacitor 26 and an inductor 27. Such a sensor is shown in even larger scale in figure 4. The variable 20 capacitor may have in one embodiment a number of interdigital conductors 28 in the form of fingers arranged on two opposing metal electrodes. A first of the electrodes 29 may be arranged on the compressible wall 24 while a second of the electrodes 31 may be fixed in 25 relation to the wall 32 of the blood circuit, e.g. may be affixed to an interior wall of a tubing line 50 or a drip chamber 15. As the pressure outside the container varies the compressible wall of the container will move and accordingly the first electrode 29 and the second 30 electrode 31 will move in relation to each other and thus the capacitance will vary. The resonance frequency of the resonance circuit constituted by the capacitor and the inductor will then vary in accordance with the capacitance of the capacitor.

35 Outside the blood circuit an exciter antenna 33 in figure 3 is arranged connected to a tunable oscillator 34 which may be controlled by a detector. The oscillator may

drive the antenna to emit electromagnetic radiation at one or more different frequencies. In one embodiment the detector may use the grid-dip oscillator technique according to which technique the oscillator frequency is 5 swept over the resonance frequency of the sensor, or other techniques for analyzing resonance frequencies of LC circuits. The oscillator is inductively coupled to the sensor and at the resonance frequency the sensor will be energized and thereby drain energy from the external 10 circuit. A current-dip in the oscillator circuit may then be detected. The resonance frequency of the oscillator circuit may then be detected and may be transformed into a pressure by an earlier established relationship between the frequency of the dip frequency and the fluid 15 pressure.

A pressure sensor 500 will now be described with reference to figures 5 a-d. Figure 5a shows the sensor 500 in perspective view and figures 5b-d shows the sensor 500 in cross section.

20 The sensor 500 comprises a substrate 501 on which a lid 502 is arranged. A cavity 503 is formed between the substrate 501 and the lid 502, whereby the substrate 501 and the lid 502 form walls of the cavity 503, defining a container. The substrate 501 and the lid 502 are made of 25 an electrically isolating material and the cavity 503 has been formed by way of, e.g., micro machining, as is known in the art. The cavity 503 is closed in the sense that no exchange of gas and liquid is possible between the cavity 503 and the outside of the cavity 503. The cavity is also 30 compressible, where the term compressible is used in the meaning that the volume of the cavity 503 may increase as well as decrease depending on the surrounding pressure.

A first electrode 504 and a second electrode 505 are arranged on two opposing walls of the cavity 503 forming 35 a capacitive arrangement. These electrodes 504,505 form, together with an inductor 506, a resonance circuit

similar to the one described above in connection with figures 3 and 4.

Figure 5c illustrates a situation where the sensor 500 is located in an environment in which the pressure is 5 higher than the pressure inside the closed cavity 503. This leads to a net pressure force 510 acting on the lid 502 resulting in a decrease of the volume of the cavity 503. Consequently, the two electrodes 504,505 are brought closer to each other, changing the capacitance of the 10 electrode arrangement and thereby changing the resonance frequency of the resonance circuit.

Figure 5d illustrates a situation where the sensor 500 is located in an environment in which the pressure is lower than the pressure inside the closed cavity 503. 15 This leads to a net pressure force 520 acting on the lid 502 resulting in an increase of the volume of the cavity 503. Consequently, the two electrodes 504,505 are brought further away from each other, changing the capacitance of the electrode arrangement and thereby changing the 20 resonance frequency of the resonance circuit.

An alternative embodiment of a sensor in a device according to the present invention is shown in figure 6. The sensor 60 comprises a container 61 having a compressible deflectable wall 62 on which a first 25 electromagnetic wave reflector or mirror 63 is arranged. The other walls of the pressure sensor may be rigid. A second reflecting or semi reflecting surface 64 is arranged between the wall of the blood circuit and the first reflector. The sensor further comprises a distance 30 measuring device 65 with an electromagnetic wave emitter, which is arranged to emit an electromagnetic wave beam 66. The electromagnetic wave beam is partly reflected in the semi-reflecting surface and is detected at the distance measuring device 65. The part of the 35 electromagnetic wave beam that passes the semi-reflecting mirror is reflected by the first reflector. By comparing the distance between the distance measuring device 65 and

the first mirror 63 with the distance between the distance measuring device 65 and the semi-reflecting mirror 64 it is possible to determine the distance between the first mirror and the semi-reflecting mirror.

5 The distance between the first mirror 63 and the semi-reflecting mirror is dependent on the pressure outside the pressure sensor within the blood circuit. The pressure may thus be determined from an earlier measurement of the distance as a function of pressure.

10 The dashed line 67 shows the deflectable wall in a deflected position with a pressure applied to the sensor. The second dashed line 99 shows the deflectable wall in a second deflected position with a negative pressure, i.e. a pressure below the pressure within the pressure sensor,

15 applied to the sensor. As an alternative the compressible container may be made very small. The size of the container may according to this embodiment be determined by using waves which are scattered from the container. From the scattered waves the size of the container and

20 consequently the pressure may be determined. The waves may be electromagnetic or sonic. In case the waves are electromagnetic they may be optical waves or waves outside the optical region.

After manufacture of the pressure sensor there might 25 be a wish to test it so that one may be certain that it functions properly. One way of doing this is to apply a pressure to the sensor and measure the resonance frequency of the sensor. The sensor is made to have a certain resonance frequency without any applied pressure. The 30 sensor is a closed container with a reference pressure inside. If the pressure sensor has a different resonance frequency when a pressure is applied to the sensor this may be taken as an indication that the pressure sensor is functioning. However, it may be that the pressure sensor 35 has a different resonance frequency without any applied pressure and still is non-functioning. Thus, in order to be more certain at least two different testing pressures

may be applied to the sensor while the resonance frequency is measured.

The pressure may be applied in a number of different ways. According to one alternative the pressure is applied by means of sonic waves such as ultrasound. It is of course also possible to apply the pressure as a static pressure. This may, however, be complicated as it may be that the pressure may better be applied in a pressure chamber.

10 Figure 7 schematically shows a patient 70 during peritoneal dialysis during which a disposable device in the form of a catheter for intraperitoneal dialysis is used. A catheter 71 connects a first fluid container 72 and a second fluid container 73 to the patient 70. A 15 pressure sensor 74 as described above is arranged on the catheter 71 inside the abdominal cavity of the patient 70. A transceiver 76 with an antenna 77 is arranged outside the patient and is arranged to send out an electromagnetic signal as described above.

20 Figure 8 shows cross sections of ends of the catheter inside the abdominal cavity and shows the pressure sensor arranged in different positions in relation to the end of the catheter. In figure 8a the pressure sensor 74 is arranged on the outside of the 25 catheter 71 while in figure 8b the pressure sensor 74 is arranged on the inside of the catheter 71. In figure 8c the pressure sensor is arranged on the inside of the catheter on the inside of an extra membrane 75.

30 By trimming during manufacturing of the pressure sensor it may be given different resonant frequencies which can thus be used to distinguish between different disposable sets. Thus, different tubing sets for use on the same machine may be identified as different tubing sets by discernment of the different resonant frequencies. Moreover, different processes may also make use hereof.

As mentioned above the calibration at manufacturing and/or at the beginning of use at startup of a dialysis session can also provide for ensuring that the pressure sensor is working. This can be a function test like

5 process to see if a proper response to the application of varying pressures by the blood pump or other mechanical alteration. The mechanical alteration may be the app-
10 liance of a mechanical force to test the electronic response frequency or the optical response frequency in case the sensor is arranged for optical detection of the pressure. The force for altering the sensor mechanically may be applied, e.g., by applying an ultrasound wave on the sensor.

The described embodiments are intended as examples
15 only and may be modified by the man skilled in the art in a number of different ways without departing from the scope and the spirit of the invention which is defined by the appending claims.

For example the resonant sensor described above may
20 be modified in that the inductance is made variable while the capacitance is fixed.

CLAIMS

1. A device for containing or transporting medical and/or biological fluid, said device comprising at least one sensor capable of sensing at least a first characteristic of the fluid, said sensor also capable of wireless communication of information where said information is related at least to the sensed characteristic of the fluid.
- 5 2. A device according to claim 1, where the device forms part of an extracorporeal blood circuit.
- 10 3. A device according to claim 1, where the device forms part of an intraperitoneal dialysis system.
4. A device according to any of claims 1-3, where said device is a disposable device.
- 15 5. A device according to claim 1, where said sensor is capable of sensing pressure.
6. A device according to claim 5, where the sensor comprises a compressible closed container, the compression or expansion of which is indicative of the pressure.
- 20 7. A device according to claim 6, where the pressure sensor comprises components in the form of a capacitance and an inductance, of which components at least one is a variable component which varies with the compression and/or expansion of the container, said capacitance and inductance forming a resonance circuit for an applied electromagnetic wave.
- 25 8. A device according to claim 7, wherein the capacitance is variable.
- 30 9. A device according to any of claims 6 to 8, wherein the container has the form of a substantially rigid box with a membrane on one side.
10. A device according to any of claims 7 to 9, wherein a part of the variable component is arranged on the membrane.
- 35

11. A device according to any of claims 7 to 10, wherein a part of the variable component varies with the movement of the membrane.
12. A device according to any of claims 7 to 11, 5 wherein a part of the variable component is formed from or by the membrane.
- *13. A device according to any of claims 1 to 6, wherein the container has a reflecting side arranged for the reflectance of waves from an emitter.
- 10 14. A device according to claim 13, wherein the waves are electromagnetic.
15. A device according to claim 14, wherein the waves are optical.
16. A device according to claim 13, wherein the 15 waves are mechanical.
17. A device according to claim 16, wherein the waves are sonic waves.
18. A device according to any one of claims 13 to 17, wherein the container has two reflecting surfaces of 20 which one is arranged on a compressible wall of the container.
19. A device according to any of the preceding claims, wherein the sensor at least partly is made of silicon or quartz.
- 25 20. A device according to any of the preceding claims, wherein the container is micromachined.
21. A device according to claim 20, wherein the container comprises two micromachined parts that together form the container of which parts at least one comprises 30 a compressible wall.
22. A device according to claim 21, wherein each one of the parts incorporates a conductive layer on sides which are arranged opposing each other and which are insulated from each other.
- 35 23. A device according to any of the preceding claims, wherein the device is configured to be indicative of the intended use of the device.

24. A device according to claim 23, wherein the resonance frequency of the device is indicative of the intended use of the device.
25. A device according to any one of the preceding 5 claims, wherein the pressure sensor is arranged to be in fluid communication with the biological fluid within the device during use.
26. A device according to any one of the preceding claims, wherein the pressure sensor is arranged within 10 the device.
27. Use of a device according to any one of the preceding claims during extracorporeal biological fluid management.
28. Use according to claim 27, wherein the fluid is 15 blood.
29. Use according to claim 27 or 28, wherein the management is dialysis.
30. Use of a device according to any one of claims 1 to 26 during management of intracorporeal biological 20 fluids.
31. Use of a device according to claim 30, wherein the management is peritoneal dialysis.
32. A system for managing fluids, comprising a device according to any of claims 1 to 26.

25

ABSTRACT

A biological fluid device comprises a pressure sensor, which is arranged on the device. The pressure
5 sensor comprises a compressible closed container, the compression of which is indicative of the pressure, and is capable of wireless communication.

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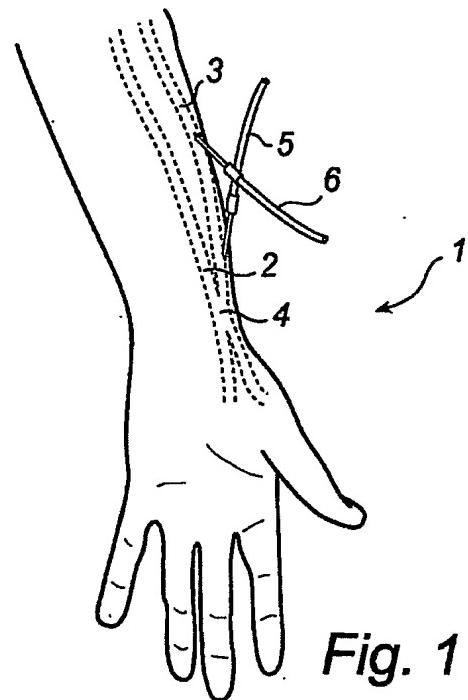


Fig. 1

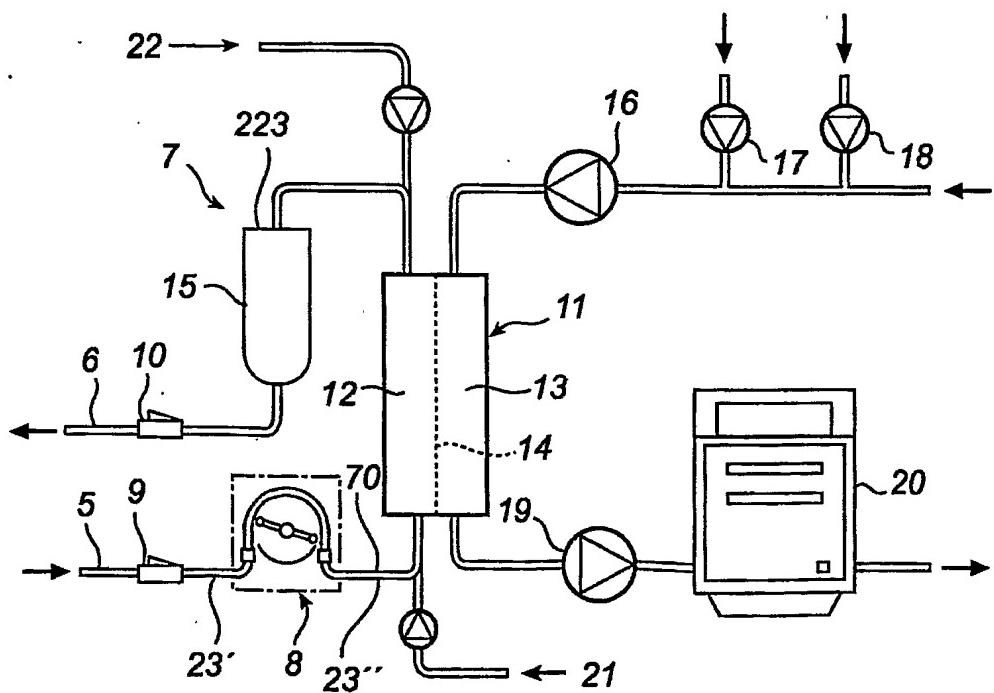


Fig. 2

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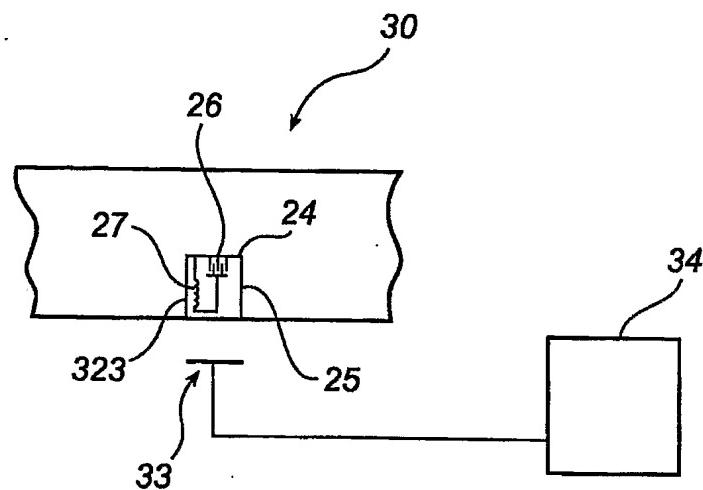


Fig. 3

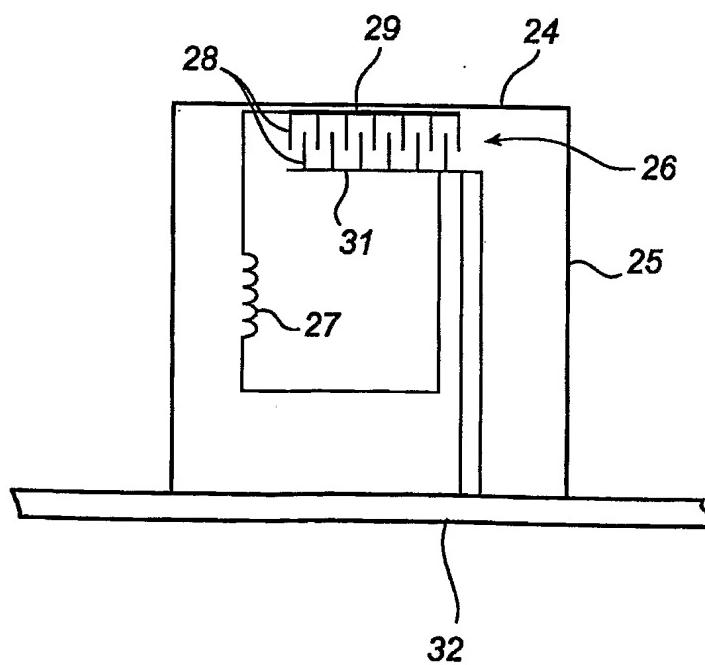


Fig. 4

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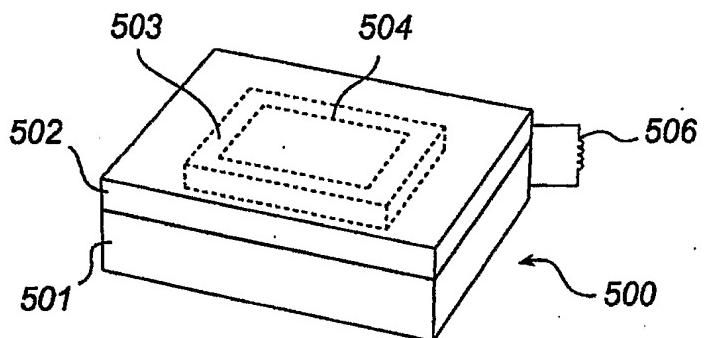


Fig. 5a

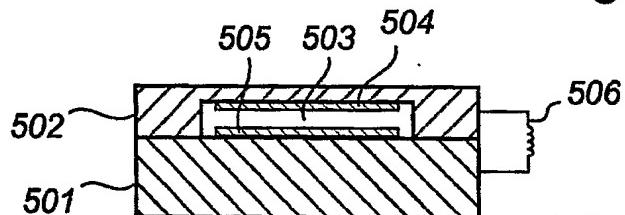


Fig. 5b

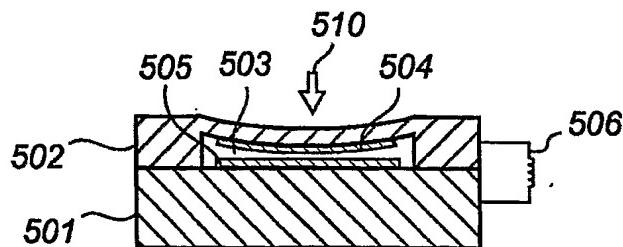


Fig. 5c

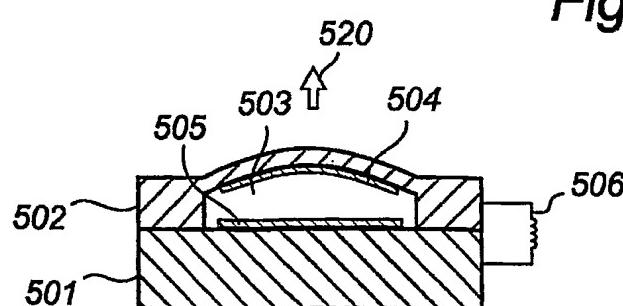


Fig. 5d

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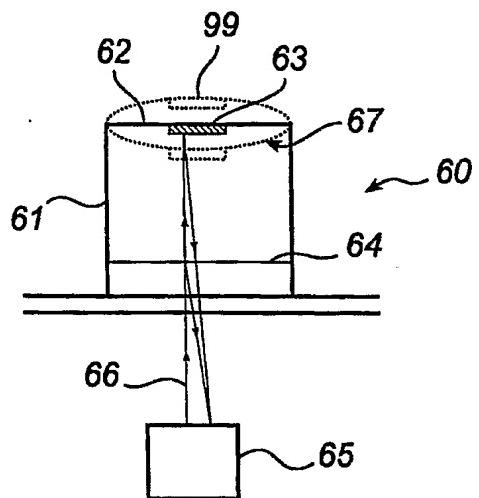


Fig. 6

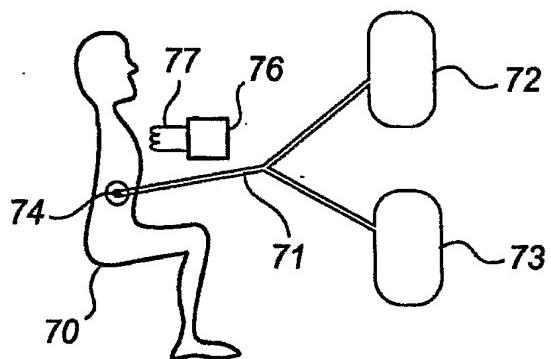


Fig. 7

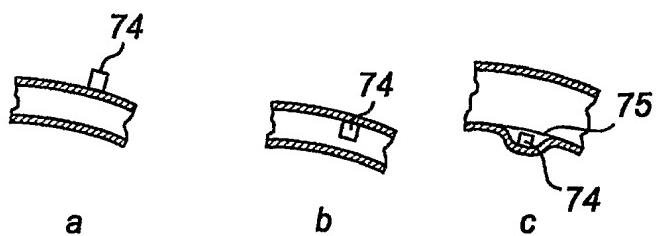


Fig. 8